UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,378	11/27/2006	David Keith James	305832-01003	8440

64770 7590 10/30/2007

MOMKUS MCCLUSKEY MONROE MARSH & SPYRATOS, LLC
3051 OAK GROVE ROAD
SUITE 220
DOWNERS GROVE, IL 60515-1181

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
4123	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,378	JAMES ET AL.	
	Examiner	Art Unit	
	Nicole F. LaVert	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. 10/595,378.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The following Application Nos. must be updated in reference to the applications current status; WO2001/26545, EP1220640, & AU20007673-A (pp 12, line 13). Appropriate corrections are required.

Drawings

2. The drawings are objected to because the reference numbers "81" and "82" of Figure 8, according to the disclosure, should be switched, so that the "Event data" corresponds to the reference number "82", and the "ECG data" corresponds to the reference number "81," (pp 16, line 8). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claims 1-21** are objected to because of the following informalities: In claim 1, line 1 "Apparatus" should read, "An apparatus". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

5. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 2, 6, 10, 15-16, 23, 25-26, 29, 35, 43, 48, & 50-52** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. **Claims 2, 10, 23, 29, 48, & 52** recites the limitation "the maternal abdomen" in reference to the electrode positioning claimed. There is insufficient antecedent basis for this limitation in the claims.

8. **Claims 6, 26, 43, & 51** recites the limitation "the QRS complex" in reference to the fetal ECG data claimed. There is insufficient antecedent basis for this limitation in the claims.

9. **Claims 15 & 34** recites the limitation "the positive and/ or negative energy" in reference to the fetal ECG complex waveform claimed. There is insufficient antecedent basis for this limitation in the claims.

10. **Claims 16 & 35** recites the limitation "the relative quantities" in reference to the positive and negative energy claimed. There is insufficient antecedent basis for this limitation in the claims.

11. **Claims 25 & 50** recites the limitation "the maternal ECG complex" in reference to the received waveform claimed. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 101

12. **Claims 1-21 & 40-47** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. **Claim(s) 1, 10, 40 & 44** are directed to nonstatutory subject matter, due to the claims reciting a part of the human body. As suggested, in claims 1, 10, 40 & 44, where is states that the electrodes are "attached to a maternal body," the claims should read "adapted to be attached to a maternal body."

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **Claims 1-6, 22-26, 40-43, 45-47, 48-51 & 53-54** are rejected under 35 U.S.C. 102(b) as being anticipated by Nagel et al. (US 4211237 A).

For **claim 1**, Nagel et al. discloses, apparatus for monitoring fetal behaviour comprising [fetomaternal electrocardiogram-see e.g., (col 3, line 42)]: an input for receiving ECG data (Figure 1, 201) from a set of electrodes attached to a maternal body [(col 9 & 10, lines 62-68 &

1-4) & (Figure 2, 301-303)]; a waveform pre-processor [microprocessor-see e.g., (Figure 3b, 33)] for identifying a succession of fetal ECG complex waveforms within the received data (col 3, lines 43-45); a waveform processor (Figure 3b, 33) for determining differences in the succession of fetal ECG complex waveforms over time (col 3, lines 45-53); and an event logger [stored sample/ memory-see e.g., (col 3, lines 50) & (Figure 3b, 7)] determining from the determined differences (col 3, lines 45-53) a number of fetal movements during the period of time (col 11, lines 50-61).

In reference to **claim 2**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 further including a plurality of electrodes for positioning at different locations on the maternal abdomen [(col 9 & 10, lines 62-68 & 1-4) & (Figure 2, 301-303)].

In reference to **claim 3**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 2 in which the number of electrodes is two (Figure 2, 301-303).

In reference to **claim 4**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 in which the waveform pre-processor (Figure 3b, 33) includes a discriminator for discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform [Amplitude discriminator & f & m-see e.g., (col 2, lines 35-42) & (Figure 2, 306)].

In reference to **claim 5**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 4, in which waveform pre-processor (Figure 3b, 33) includes means for subtracting the maternal ECG complexes from the received waveform (Figure 1, 204).

In reference to **claim 6**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 1 in which the waveform pre-processor (Figure 3b, 33) comprises means for identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

For **claim 22**, Nagel et al. discloses, a method for monitoring fetal behaviour comprising (col 3, lines 30-31): (i) obtaining fetal ECG data over a period of time (Figure 2, 301-303); (ii) identifying a succession of fetal ECG complex waveforms within the data (col 3, lines 43-45); (iii) determining differences in the succession of fetal ECG complex waveforms over time; and (iv) determining from the determined differences (col 3, lines 45-53) a number of fetal movements during the period of time (col 11, lines 50-61).

In reference to **claim 23**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 22 in which step (i) comprises obtaining fetal ECG data from a plurality of electrodes positioned at different locations on the maternal abdomen (Figure 2, 301-303 & 304).

In reference to **claim 24**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 23 in which step (ii) includes the step of discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform (col 10, lines 5-50).

In reference to **claim 25**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 24 in which step (ii) includes subtracting the maternal ECG complexes from the received waveform (Figure 1, 204).

In reference to **claim 26**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 22 in which step (ii) comprises identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

For **claim 40**, Nagel et al. discloses, an apparatus for determining fetal spatial presentation and/or position within the uterus (col 3, line 42) comprising: an input for receiving ECG data (Figure 1, 201) from a set of electrodes attached to a maternal abdomen in a predetermined configuration (Figure 2, 301-303 & 304); a waveform pre-processor (Figure 3b,

33) for identifying a number of fetal ECG complex waveforms within the data (col 3, lines 43-45); a memory (Figure 3b, 7) storing a plurality of fetal ECG complex templates (col 3, lines 39-40) each corresponding to a specific fetal spatial presentation and/or position (col 3, lines 40-50); a comparator (Figure 3b, 8) for comparing each of the received waveforms with a set of the plurality of fetal ECG complex templates (col 3, lines 39-40) ascribed to the predetermined electrode configuration (Figure 2, 301-303) and determining a template from said set of templates that best matches the identified fetal ECG waveforms (col 3, lines 40-50).

In reference to **claim 41**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 40 in which the waveform pre-processor (Figure 3b, 33) comprises means for discriminating between maternal ECG complexes and fetal ECG complexes in the received ECG data [(col 2, lines 35-42) & (Figure 2, 306)].

In reference to **claim 42**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 41 in which the waveform pre-processor (Figure 3b, 33) includes means for subtracting the maternal ECG complexes from the received ECG data (Figure 2, 204).

In reference to **claim 43**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 40 in which the waveform pre-processor (Figure 3b, 33) comprises means for identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

In reference to **claim 45**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 40 further including a set of said electrodes for attachment to the maternal abdomen (Figure 2, 301-303).

In reference to **claim 46**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 45 in which the number of electrodes is two (Figure 2, 301-303).

In reference to **claim 47**, Nagel et al. discloses, the apparatus (col 3, line 42) of claim 40 in which each template (col 3, lines 39-40) corresponds to a specific fetal spatial presentation and position relative to a specific electrode configuration (col 3, lines 40-50).

For **claim 48**, Nagel et al. discloses, a method for determining fetal spatial presentation and/or position within the uterus (col 3, lines 30-31) comprising: (i) obtaining fetal ECG data from a plurality of electrodes positioned on the maternal abdomen in a predetermined configuration (Figure 2, 301-303 & 304); (ii) identifying a number of fetal ECG complex waveforms within the data (col 3, lines 43-45); (iii) comparing each of the waveforms (Figure 3b, 8) with a set of predetermined fetal ECG complex templates (col 3, lines 39-40) ascribed to the predetermined electrode configuration (Figure 2, 301-303); and (iv) determining a template from said set of templates that best matches the identified fetal ECG waveforms (col 3, lines 40-50).

In reference to **claim 49**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 48 in which step (ii) includes the step of discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform [(col 2, lines 35-42) & (Figure 2, 306)].

In reference to **claim 50**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 49 in which step (ii) includes subtracting the maternal ECG complexes from the received waveform (Figure 1, 201).

In reference to **claim 51**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 48 in which step (ii) comprises identifying the QRS complex in the fetal ECG data (col 3, lines 39-42).

In reference to **claim 53**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 48 in which the number of electrodes is two (Figure 2, 301-303).

In reference to **claim 54**, Nagel et al. discloses, the method (col 3, lines 30-31) of claim 48 in which each template (col 3, lines 39-40) corresponds to a specific fetal spatial presentation and position relative to a specific electrode configuration (col 3, lines 40-50).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **Claims 7-11, 27-30, 44, & 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) in view of Marossero et al. (US 20050267376).

In reference to **claims 7, 27, 44, & 52** Nagel et al. shows all the features of the instantly claimed invention as discussed above including a comparator [Nagel, Amplitude matching device-see e.g., (Figure 3b, 8)].

Nagel et al. fails to disclose ECG templates corresponding to different fetal presentations.

Marossero et al. teaches a variety of templates corresponding to different fetal presentations [0190] and comparing each of the identified fetal ECG waveforms with a set of predetermined ones of the fetal ECG complex templates [Marossero, 0183] and determining at

least one template from said set of templates that best matches each identified fetal ECG waveform [Marossero, 183].

It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated a variety of templates corresponding to different fetal presentations in the apparatus of Nagel et al., in light of the teachings of Marossero, in order to provide accurate fetal presentation by the highest correlation coefficient [Marossero, 0183].

In reference to **claim 8**, Nagel et al. teaches in view of Marossero et al., the apparatus (Nagel, col 3, line 42) of claim 7 in which the memory (Figure 3b, 7) stores a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position relative to a specific electrode configuration [Marossero, 0183].

In reference to **claim 9**, Nagel et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 in which the event logger (Figure 3b, 7) records occasions on which the determined template changes (col 3, lines 53-61).

In reference to **claim 10**, Nagel et al. in view of Marossero et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 further includes means for selecting the set of predetermined fetal ECG templates according to a configuration of ECG electrodes positioned on the maternal abdomen [Marossero, 0183].

In reference to **claim 11**, Nagel et al. in view of Marossero et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 7 in which the set of predetermined fetal ECG templates (col 3, lines 39-40) includes templates corresponding to at least cephalic presentation (Marossero, Figure 12A), breech presentation (Figure 12B), shoulder dorsoanterior presentation and shoulder dorsoposterior presentation (Figure 12C).

In reference to **claim 28**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which step (iv) comprises determining the number of successive occasions on which the determined template changes during the period of time [Marossero, 0190].

In reference to **claim 29**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which the set of predetermined fetal ECG templates is selected according to a configuration of ECG electrodes positioned on the maternal abdomen [Marossero, 0183].

In reference to **claim 30**, Nagel et al. in view of Marossero et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which the set of predetermined fetal ECG templates (col 3, lines 39-40) includes templates corresponding to at least cephalic presentation (Marossero, Figure 12A), breech presentation (Figure 12B), shoulder dorsoanterior presentation and shoulder dorsoposterior presentation (Figure 12C).

17. **Claims 12-14, & 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4, 211,237) in view of Beach et al. (US 5,088,498).

Nagel et al. shows all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to teach a means for detecting phase changes in respect to the fetal ECG complex waveforms.

Beach et al. teaches the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (col 4, lines 5-11)

It would have been obvious to one of ordinary skill in the art at the time of the invention, to have included a phase detector which determines the approximate phases for ultrasounds

reflected at each of several different depth, in the apparatus of Nagel et al., as taught by Beach et al. in order to provide a precise indication for the distance traveled by the reflective tissue (Beach, col 4, lines 10-11).

In reference to **claim 12**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 1 in which the waveform processor (Figure 3b, 33) comprises means for detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] between successive fetal ECG complex waveforms (Nagel, col 3, lines 40-45).

In reference to **claim 13**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 12 in which the waveform processor (Figure 3b, 33) comprises means for detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] of one or more predetermined magnitudes between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

In reference to **claim 14**, Nagel et al. in view of Beach et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 12 in which the event logger (Figure 3b, 7) records occasions on which a phase change occurs [Beach, (col 4, lines 5-11) & (Figure 3)].

In reference to **claim 32**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 in which step (iii) comprises detecting phase changes [Beach, (col 4, lines 5-11) & (Figure 3)] of one or more predetermined magnitudes between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

18. **Claims 15-21 & 34-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) in view of Oriol et al. (US 5,596,993).

Nagel et al. shows all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to teach a manner in which differences in fetal complex waveforms are detected by change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference. Nagel et al. also fails to teach means for providing a display, a fetal heart rate monitor, an alarm and an electronic interface associated with monitoring fetal behavior.

Oriol et al. teaches a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [(col 9, lines 60-67) & (Figure 5A)]. Oriol et al. also teaches a monitoring system, which incorporates a display, a fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board (Figure 14, 108, 102, & 116-120).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system, which incorporates a display, fetal monitor, and an A/D convert associated with a digital signal processing board and neural network board, in the system of Nagel et al., as taught by Oriol et al., thereby detecting differences in the fetal complex waveforms by change in the positive and or negative energy of the fetal ECG complex waveform relative to a reference, in order to show the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate (Oriol, col 9, lines 40-42 & 63-67), and in order to provide output data, such as warnings and recommendation, to the clinician (Oriol, col 19, lines 39-40 & 54-56).

In reference to **claim 15**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 1 in which the waveform processor (Figure 3b, 33) is adapted to determine differences in fetal complex waveforms (col 3, lines 40-50) by detecting change in the positive and/or negative energy of a fetal ECG complex waveform relative to a reference (Oriol, Figure 5A).

In reference to **claim 16**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 15 in which the waveform processor (Figure 3b, 33) is adapted to determine differences in fetal complex waveforms (col 3, lines 40-50) by detecting changes in the relative quantities of positive and negative energy of a fetal ECG complex waveform relative to a baseline (Oriol, Figure 5A).

In reference to **claim 17**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, col 3, line 42) of claim 15 in which the reference comprises a previous or average fetal ECG complex waveform [Oriol, (col 6, lines 5-14) & (Figures 1-4)].

In reference to **claim 18**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including a display for displaying a count of the number of fetal movements detected [Oriol, (col 20, lines 22-32) & (Figure 14, 108)].

In reference to **claim 19**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 wherein the waveform processor (Figure 3b, 33) further includes a fetal heart rate monitor (Oriol, Figure 14, 102).

In reference to **claim 20**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including an alarm for indicating if the number of fetal movements during a period of time falls below a predetermined threshold further including an

alarm for indicating if the number of fetal movements during a period of time falls below a predetermined threshold [Oriol, (col 19, lines 23-29) & (Figure 13, 86)].

In reference to **claim 21**, Nagel et al. in view of Oriol et al. teaches, the apparatus (Nagel, Col 3, line 42) of claim 1 further including a memory for storing fetal movement event data (Figure 3b, 7) and an electronic interface for downloading said event data to a remote device [Oriol, A/D, DSP, and neural network board-see (Figure 14, 116-120)]. The examiner is interpreting the A/D, DSP, and neural network boards as performing the same tasks as an electronic interface as taught by the instantly claimed invention.

In reference to **claim 34**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 in which the differences determined (col 3, lines 40-50) in step (iii) comprises change in the positive and/or negative energy of a fetal ECG complex waveform relative to a reference (Oriol, Figure 5A).

In reference to **claim 35**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 34 in which the differences determined (col 3, lines 40-50) in step (iii) comprise changes in the relative quantities of positive and negative energy of a fetal ECG complex waveform relative to a baseline (Oriol, Figure 5A).

In reference to **claim 36**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 34 in which the reference comprises a previous or average fetal ECG complex waveform [Oriol, (col 6, lines 5-14) & (Figures 1-4)].

In reference to **claim 37**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of displaying or logging a cumulative count of the number of fetal movements within the period of time (Oriol, Figure 13 & 14, 108).

In reference to **claim 38**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of monitoring fetal heart rate (Oriol, Figure 14, 102).

In reference to **claim 39**, Nagel et al. in view of Oriol et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 22 further including the step of indicating an alarm condition if the number of fetal movements during the period of time falls below a predetermined threshold [Oriol, (col 19, lines 23-29) & (Figure 13, 86)].

Claim

19. **Claims 31 & 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel et al. (US 4,211,237) as applied to claim 27 above, and further in view of Beach et al. (US 5,088,498).

Nagel et al. discusses all the features of the instantly claimed invention as discussed above.

Nagel et al. fails to discuss a means for detecting phase changes in respect to the fetal ECG complex waveforms.

Beach et al. teaches the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (col 4, lines 5-8)

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Nagel et al with the use of a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depth as taught by Beach et al. in order to provide a means for detecting phase changes in respect to the fetal ECG complex waveforms.

In reference to **claim 31**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 27 in which step (iii) comprises detecting phase changes (Beach, Figure 3) between successive fetal ECG complex waveforms (Nagel, col 11, lines 10-25).

In reference to **claim 33**, Nagel et al. in view of Beach et al. teaches, the method (Nagel, col 3, lines 30-31) of claim 31 in which step (iv) comprises determining the number of successive occasions (col 11, lines 10-25) on which a phase change occurs during the period of time (Beach, Figure 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole F. LaVert whose telephone number is 571-270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N.F.L.

ESSAMA OMGBA
PRIMARY EXAMINER